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EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,307	GRIFFITH ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *4,9,10 and 13-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03032004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11 and 12, drawn to nucleic acid, vector, host cell, classified in class 435, subclass 325.

II. Claims 9 and 10, drawn to pharmaceutical composition of nucleic acid, classified in class 514, subclass 44.

III. Claims 13-17, drawn to protein and pharmaceutical composition, classified in class 514, subclass 12.

IV. Claim 18, drawn to cell line producing antibody, classified in class 435, subclass 326.

V. Claim 19, drawn to antibody, classified in class 530, subclass 387.1.

VI. Claims 20-23, drawn to methods comprising detecting a mutation in a gene encoding TDC2, classified in class 435, subclass 6.

VII. Claims 24-27, drawn to methods comprising detecting a mutation in TDC2, classified in class 435, subclass 7.1.

VIII. Claim 29, drawn to gene therapy method of treating an animal for hearing loss comprising administering nucleic acid encoding TDC2, classified in class 514, subclass 44.

IX. Claim 30, drawn to method of treating an animal for hearing loss comprising administering TDC2, classified in class 514, subclass 12.

X. Claim 31, drawn to method of identifying an agent which interacts with a TDC2 gene in a cell, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. The DNA of Group I and the pharmaceutical composition thereof of Group II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because, in addition to the DNA encoding the protein the pharmaceutical composition would need to include additional DNA such as a promoter, stop signals and some kind of mechanism to get the expressible DNA to the proper location for expression. The subcombination has separate utility such as hybridization assays to detect the gene in a sample.

3. The DNA of group I is related to the protein of group III by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes,

such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

4. The DNA of Group I and the cell line producing antibody of Group IV are related by virtue of the protein that is encoded by the DNA and necessary to tell the cell what antibody to produce. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

5. The DNA of Group I and the antibody of Group V are related by virtue of the protein that is encoded by the DNA and necessary for the production of the antibody. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

6. The DNA of Group I and the method of detecting a mutation in a gene encoding TDC2 of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in

a materially different process of using that product such as producing TDC2 recombinantly.

7. The DNA of Group I is related to the method of detecting a mutation in TDC2 of Group VII by virtue of the fact that the protein is encoded by the DNA. The inventions are distinct, however because the DNA is not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

8. The DNA of Group I and the method of treating an animal for hearing loss comprising administering nucleic acid encoding TDC2 of Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as producing TDC2 recombinantly.

9. The DNA of Group I is related to the method of treating an animal for hearing loss comprising administering TDC2 of Group IX by virtue of the fact that the protein is encoded by the DNA. The inventions are distinct, however because the DNA is not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

10. The DNA of Group I and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as producing TDC2 recombinantly.

11. The pharmaceutical composition comprising DNA of Group II and the inventions of Groups III-VII, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the pharmaceutical composition comprising DNA of Group II and the protein, pharmaceutical composition of Group III, the cell line producing antibody of Group IV, the antibody of Group V, the methods comprising detecting a mutation in a gene encoding TDC2 of Group VI, the methods comprising detecting a mutation in TDC2 of Group VII, the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have

acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

12. The pharmaceutical composition comprising DNA of Group II and the method of treating an animal for hearing loss comprising administering nucleic acid encoding TDC2 of Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as assaying for the gene encoding TDC2.

13. The protein of Group III and the cell line producing antibody of Group IV are related by virtue of being the cognate antigen necessary for the production of antibody. However, the protein itself is not used by the host cell for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

14. The protein of group III is related to the antibody of group V by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are

distinct inventions because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

15. The protein of Group III and method of detecting a mutation in a gene encoding TDC2 of Group VI are related because the polynucleotide to be detected encodes the protein. Clearly, the protein is not required for the practice of the method of detection of the polynucleotide, nor are they disclosed as capable of use together. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

16. Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as treating hearing loss.

17. The protein of Group III and the gene therapy method of Group VIII are related because the polynucleotide used in the method encodes the protein. Clearly, the protein

is not required for the practice of the gene therapy method, nor are they disclosed as capable of use together. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

18. The protein of Group III and the method of treating an animal for hearing loss comprising administering TDC2 of Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as acting as the cognate antigen for the production of antibody.

19. The protein of Group III and method of identifying an agent which interacts with a TDC2 gene in a cell by measuring the expression level of the gene encoding TDC2 of Group X are related because the protein to be detected is encoded by the DNA whose level of expression is being detected. Clearly, the protein is at best a passive participant in the method of detection of the level of expression of the polynucleotide, but takes no part in the expression of itself. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

20. The cell line producing antibody of Group IV and the inventions of Groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the cell line producing antibody of Group IV and the methods comprising detecting a mutation in a gene encoding TDC2 of Group VI, the methods comprising detecting a mutation in TDC2 of Group VII, the gene therapy method of Group VIII, the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

21. The cell line producing antibody of Group IV and the antibody of Group V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the antibody is made by the cell but does not tell the cell to make

itself, that information is provided by the specific antigen. The subcombination has separate utility such as assaying for the antigen in an *in vitro* environment.

22. The antibody of Group V and the inventions of Groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group V and the methods comprising detecting a mutation in a gene encoding TDC2 of Group VI, the methods comprising detecting a mutation in TDC2 of Group VII, the gene therapy method of Group VIII, the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

23. The method comprising detecting a mutation in a gene encoding TDC2 of Group VI and the inventions of Groups VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method comprising detecting a mutation in a gene

encoding TDC2 of Group VI and the methods comprising detecting a mutation in TDC2 of Group VII, the gene therapy method of Group VIII, the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

24. The method comprising detecting a mutation in TDC2 of Group VII and the inventions of Groups VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method comprising detecting a mutation in TDC2 of Group VII and the gene therapy method of Group VIII, the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

25. The gene therapy method of Group VIII and the inventions of Groups IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the gene therapy method of Group VIII and the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

26. The method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the invention of Group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of treating an animal for hearing loss comprising administering TDC2 of Group IX and the method of identifying an agent which interacts with a TDC2 gene in a cell of Group X do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These

groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

27. Claim 28 link(s) inventions VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 28. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

28. The presence of multiple polynucleotide and polypeptide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable

of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect between human (SEQ ID NO: 3 encoding SEQ ID NO: 4) and mouse TDC2 (SEQ ID NO: 7 encoding SEQ ID NO: 8) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. This is not to be construed as an election of species, but rather an election between patentably distinct inventions. Evidence showing that the sequences are somehow related such that one search query could cover all of them might be effective to negate this requirement.

29. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be

fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

30. During a telephone conversation with Melissa Kolom on November 9, 2005 and another conversation a few days later, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8, 11 and 12 with regard to human TDC2, SEQ ID Nos.: 3 and 4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 9, 10 and 13-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

31. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

32. The information disclosure statement filed March 3, 2004 has been considered. Please see the attached initialed PTO-1449. Reference AJ was not considered since no copy of the reference was found in the electronic file wrapper. The references cited on pages 36 and 37 of the specification have not been considered since they have not been cited in the manner of an information disclosure statement.

33. Examiner notes that the term, "consisting essentially of" used in the claims has not been specifically defined in the specification and, therefore, consonant with the doctrine of giving a claim its broadest reasonable interpretation, the term has been interpreted to mean, "comprising".

Claim Rejections - 35 USC § 112, Second Paragraph

34. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35. Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are rendered indefinite by the term, "moderately stringent conditions." The term is exemplified in the specification on pages 11 and 12 but the examples are not sufficient to specify what exactly is intended to be claimed.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

36. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

37. Claims 1-3, 5-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid comprising SEQ ID NO: 3 and those encoding SEQ ID NO: 4, does not reasonably provide enablement for i) fragments of nucleic acid encoding at least 70 amino acids of SEQ ID NO: 4, ii) fragments of nucleic acid comprising at least 110 contiguous nucleotides, iii) nucleic acid that hybridizes under moderately stringent conditions to SEQ ID NO: 3 or a fragment thereof and iv) nucleic acid that shares 49% identity with SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because the number of fragments of nucleic acid encoding at least 70 amino acids of SEQ ID NO: 4 is very large, the number of fragments of nucleic acid comprising at least 110

contiguous nucleotides is very large, the number of nucleic acids that hybridize under moderately stringent conditions to SEQ ID NO: 3 or a fragment thereof is immense and the number of nucleic acids that share 49% identity with SEQ ID NO: 3 is extremely large; thus, many fragments of nucleic acid would have to be tested for some function; (2) the amount of guidance provided by the specification is zero since there is no discussion of how to use the various fragments or nucleic acids that hybridize under moderately stringent conditions or are at least 49% identical to SEQ ID NO: 3. One of skill in the art would have no idea what structural characteristics might make one fragment have activity and another have none. Indeed, there is no disclosure whatsoever of any activity nor what the fragments, etc. might be used for and, therefore, no guidance. While one of skill in the art would know how to use the fragments as probes to detect the presence of the gene encoding TDC2, there is no disclosure of which portions of SEQ ID NO: 3 might detect mutations. The absence of any correlation between any fragment and any mutation prevents said person of skill in the art from deducing which portions of nucleic acid to use. Continuing, (3) the specification is totally devoid of any working examples showing how to use any of the fragments, etc.; (4) the nature of the invention is the discovery that TDC2 plays some pivotal role in hearing. The prior art (5) shows nucleic acids that are identical to the full length of SEQ ID NO: 3 as well as nucleic acids meeting the other limitations of the claims; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low. In order to make sensible predictions one of skill in the art needs some initial data as well as some algorithm to follow to predict outcomes of the choice of fragment. As stated

above, the specification contains no information as to what the fragments, etc. actually do. With such lack of information predictability is necessarily low. Finally, (8) the claims are enormously broad because of the large number and level of diversity of the fragments of nucleic acid encoding at least 70 amino acids of SEQ ID NO: 4, fragments of nucleic acid comprising at least 110 contiguous nucleotides, nucleic acids that hybridize under moderately stringent conditions to SEQ ID NO: 3 or a fragment thereof and nucleic acids that share 49% identity with SEQ ID NO: 3.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 102

38. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

39. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any of Kurima et al. (Reference AK on the PTO-1449), Drmanac et al. or Venter et al.

Kurima et al. teach DNA encoding TMC2 that is 100% identical to SEQ ID NO: 3. See Figure 3 and the sequence alignment attached to the copy of the reference. This clearly anticipates the above claims.

Drmanac et al. teach DNA that (i) encodes the amino acid sequence of SEQ ID NO: 4 or a fragment thereof comprising at least 70 contiguous amino acids, (ii) consists essentially of the nucleotide sequence of SEQ ID NO: 3 or a fragment thereof comprising at least 1 10 contiguous nucleotides, (iii) hybridizes under moderately stringent conditions to an isolated or purified nucleic acid molecule consisting essentially of the nucleotide sequence that is complementary to SEQ ID NO: 3 or a fragment thereof, or (iv) shares 49% or more identity with SEQ ID NO: 3. See the sequence alignment attached to the back of the reference. This clearly anticipates the above claims.

Venter et al. teach Sequence No. 14417 which is DNA comprising at least 110 nucleotides of SEQ ID NO: 3 that encodes at least 70 amino acids of SEQ ID NO: 4 and would hybridize to SEQ ID NO: 3 under moderately stringent conditions. See sequence alignment attached to front page of reference. This clearly anticipates the above claims.

Claim Rejections - 35 USC § 103

40. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

41. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

42. Claims 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kurima et al. or Drmanac et al.

The teachings of the references are outlined above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the nucleic acid of the references into a vector and then into a host cell to express the protein to enable further study of the protein. Motivation is provided by Kurima et al. at page 282, right column, paragraph starting with "*TMC2* and *Tmc2* as candidate genes . . ." Motivation is provided by Drmanac et al. at page 18, line 16 – page 20, line 23 and page 24, line 27 - page 27, line 27. One of ordinary skill in the art also has a reasonable expectation of success since expression of DNA is now fairly routine.

Double Patenting

43. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

44. Claims 1-3, 5-8, 11 and 12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-9, 11, 12, 15, 16, 23 and 24 of copending Application No. 10/487,887. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

45. No claim is allowed.

46. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RAW

JON WEBER
SUPERVISORY PATENT EXAMINER